Draft Panel Questions – FFDM

One of the main objectives of the 510(k) review process is to assess substantial equivalence of a new FFDM device to one of the predicate devices (five approved PMA devices). However, there remain questions as to what combination of physical laboratory testing and clinical performance data are required to determine safety and effectiveness of the FFDM and substantial equivalence.

1. The draft guidance describes numerous physical laboratory tests to be conducted on full field digital mammography systems. Does physical laboratory testing alone provide sufficient information about safety and effectiveness of FFDM to be the only testing required of a new FFDM? If not, what are the limitations of this approach?

2. Are there conditions when mammographic features analysis (MFA), should be provided in addition to the laboratory testing described in Question 1 to support the safety and effectiveness of an FFDM?

    a. Under what conditions is a MFA needed?

    b. What should be the purpose of the MFA?
        i. Ensure that there are no unanticipated problems in the imaging system.
        ii. To provide user preference information that may be conveyed in labeling.
        iii. To provide performance information that can be a basis for clearance of an FFDM.
        iv. Other

    c. How should the MFA study be designed? Please address the following aspects of study design:
        i. patient demographics
        ii. mammographic characteristics
        iii. stress test?
        iv. critical factors to be investigated (*e.g. conspicuity, positioning*)
        v. endpoints, statistical significance needed?
        vi. blinding
        vii. any other aspects of study design you wish to address

    d. Do you have any other comments about MFA and its usefulness?

3. Are there conditions when an MRMC study should be provided in addition to the testing described in Question 2 (physical laboratory testing and MFA) to support the safety and effectiveness of an FFDM?

    a. Under what conditions is an MRMC needed?

b. What should be the purpose of the MRMC?

c. How should the MRMC be designed? Please address the following aspects of study design:
    i. patient demographics
    ii. mammographic characteristics
    iii. stress test?
    iv. endpoints, statistical significance needed? (e.g., diagnosis, agreement)
    v. blinding
    vi. any other aspects of study design you wish to address

d. Do you have any other comments about MRMC and its usefulness?

4. Based on your review of the draft guidance document, the comments received from the public, and other issues discussed in today's panel meeting, are there any other aspects of the draft guidance document that you wish to discuss or propose modifications to?